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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/824,364	04/02/2001	Ismat Ullah	HX96 (DIV)	7174

7590 12/23/2003

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EXAMINER

WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 12/23/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.



## UNITED STATES DEPARTMENT OF COMMERCE

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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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13

DATE MAILED:

This is a communication from the examiner in charge of your application.  
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## OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 9/15/07
- ☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

- ☒ Claim(s) 28-47 is/are pending in the application.
- ☐ Of the above, claim(s) 29-35 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 28, 36-47 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 10
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES--

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 28, 36-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eisman in view of Eichel et al, Hodges et al, and Shell et al.

Eisman et al teach a method of lowering cholesterol by administration<sup>of</sup> a combination of an HMG CoA reductase inhibitor and a pharmaceutical which reduces cholesterol other than by inhibiting HMG CoA reductase (abstract). Lovastatin (column 8 lines 56-59) and aspirin (column 13 line 42) are disclosed. Tablets and capsules are disclosed (column 15 line 10). Antioxidants such as ascorbic acid are disclosed (column 15 line 14).

Eichel et al., teach sustained release preparations of aspirin wherein the aspirin is uncoated as well coated<sup>as</sup> with an enteric coat (abstract). Granular drugs are specified<sub>1</sub> (column 5 line 65).

Hodges et al., teach enteric-coated pellets (abstract). Pravastatin is specified (table, column 5).

Shell et al teach a plurality of drugs carried by particulates, wherein each particulate carries one drug, to vary the release of each drug according to its half-life by varying the release rate of the particles carrying<sup>and/or</sup> each drug<sub>1</sub> the number of particles carrying the drug (column 4 line 48 column 10 line 4).

It would have been obvious to one of ordinary skill to deliver the composition of Eisman et al with the vehicle of Eichel et al., to achieve the beneficial effect of controlled release. As to coating <sup>+</sup>stains as well, Hodges et al. teach such.

It would have been further obvious to one of ordinary skill to place the two drugs of Eisman et al in separate particulates to achieve the beneficial effect of varying release individually according to half-life in view of Shell et al.

Applicants argue that Eisman et al do not teach a Statin and Aspirin. However, as stated in the description above, Eisman et al does so teach.

Applicants argue that neither secondary reference teaches applicants combination of drugs. However, again the primary reference does so teach.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Art Unit: 1617

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 308-4432. The examiner can normally be reached on Monday-Friday 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan can be reached on 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234.

Webman/tgd  
December 8, 2003

  
EDWARD J. WEBMAN  
PRIMARY EXAMINER  
GROUP 1500